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PCT

DOCKET NO.: T0509.70011US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Seiichi Araki et al.  
Serial No.: 10/506,631  
Confirmation No.: Not yet assigned  
Filed: September 3, 2004  
For: A MEDICAMENT CONTAINING A RIBOFLAVIN COMPOUND  
  
Examiner: Unknown  
Art Unit: Unknown

CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 10th day of November, 2004.

Elyse B. Pino  
Elyse B. Pino

MAIL STOP AMENDMENT  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Transmitted herewith are the following documents:

- ☒ Information Disclosure Statement
- ☒ PTO Form 1449 with cited references
- ☒ Return Receipt Postcard

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at (617) 720-3500, Boston, Massachusetts.

A check is not enclosed. If a fee is required, the Commissioner is hereby authorized to charge Deposit Account No. 23/2825. A duplicate of this sheet is enclosed.

Respectfully submitted,  
Seiichi Araki et al., Applicants

By:

Roque El-Hayek

Roque El-Hayek, Reg. No. 55,151  
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Docket No.: T0509.70011US00  
Date: 11/10/04  
xNDDx

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

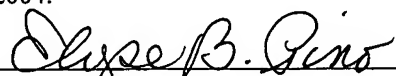
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Elyse B. Pino

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**MAIL STOP AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98**

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

**PART I: Compliance with 37 C.F.R. §1.97**

This Information Disclosure Statement has been filed within three months of the filing date of the entry of the National Stage, as set forth in 37 C.F.R. §1.491, in an International application, and before the mailing date of a first Office Action on the merits in the above-identified case.

No fee or certification is required.

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Conf. No.: Not yet assigned

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Art Unit: Unknown

PART II: Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

The above-identified U.S. application claims priority to application Serial No. PCT/JP03/02868. If the Examiner has not had the benefit of review of the file history of PCT/JP03/02868, then he/she is asked to contact the undersigned, who will provide a copy of same.

The Applicant would like to bring to the Examiner's attention the enclosed search report from a corresponding International or Foreign National Application (PCT/JP03/02868 filed March 11, 2003).

PART III: Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

Serial No.: 10/506,631  
Conf. No.: Not yet assigned

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Art Unit: Unknown


By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,  
*Seiichi Araki et al., Applicants*

By:   
\_\_\_\_\_  
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Docket No.: T0509.70011US00  
Date: 11/17/04  
xNDDx

FORM PTO-1449/A and B (Modified)  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.: 10/506,631		ATTY. DOCKET NO.: T0509.70011US00	
				FILING DATE: September 3, 2004		CONFIRMATION NO.: Not yet assigned	
				APPLICANT: Seiichi Araki et al.			
				GROUP ART UNIT: Unknown		EXAMINER: Unknown	
Sheet	1	of	2				

#### U.S. PATENT DOCUMENTS

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		

#### FOREIGN PATENT DOCUMENTS

Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
	B1	JP	11-322601		Fujimoto Brothers:KK Lek Tovarna Farmaceutskih (English Abstract attached)	11.24.1999	N
	B2	JP	8-506322		YEDA RES & DEV CO LTD (English Abstract attached)	07.09.1996	N
	B3	JP	5-201864		EISAI CO LTD (English Abstract attached)	08.10.1993	N
	B4	JP	10-29941		NEC CORP (English Abstract attached)	02.03.1998	N
	B5	WO	97/36594		EISAI CO., LTD. (English Abstract at bottom of first page)	09.10.1997	N

#### OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)	
	C1	OGAWA, MICHIO, "Cytokines Modulate Immunological Response to Surgical Insult," also translated as "New Invasion And Cytokines, A Double-Edged Sword Which Protects and Destroys the Body," Medical Sense, Tokyo (1999) (English Abstract enclosed)		N
	C2	ROGER C. BONE, "Toward A Theory Regarding The Pathogenesis Of The Systemic Inflammatory Response Syndrome: What We Do And Do Not Know About Cytokine Regulation," Crit. Care Med., Vol. 24, No. 1, pp. 163-172 (1996)		
	C3	JOHN M. LUCE et al., "Ineffectiveness Of High-Dose Methylprednisolone In Preventing Parenchymal Lung Injury And Improving Mortality In Patients With Septic Shock," A.M. Rev. Respir. Dis., Vol. 138, pp. 62-68 (1988)		
	C4	EDWARD ABRAHAM et al., "Efficacy And Safety Of Monoclonal Antibody To Human Tumor Necrosis Factor $\alpha$ In Patients With Sepsis Syndrome: A Randomized, Controlled, Double-Blind, Multicenter Clinical Trial," JAMA, Vol. 273, No. 12, pp. 934-941 (March 22/29, 1995)		
	C5	CHARLES J. FISHER, JR., M.D. et al., "Recombinant Human Interleukin 1 Receptor Antagonist In The Treatment Of Patients With Sepsis Syndrome: Results From A Randomized, Double-Blind, Placebo-Controlled Trial," JAMA, Vol. 271, No. 23, pp. 1836-1843 (June 15, 1994)		
	C6	JEAN-FRANCOIS A. DHAINAUT, M.D. et al., "Platelet-Activating Factor Receptor Antagonist BN 52021 In The Treatment Of Severe Sepsis: A Randomized, Double-Blind, Placebo-Controlled, Multicenter Clinical Trial," Critical Care Medicine, Vol. 22, No. 11, pp. 1720-1728 (November 1994)		

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				APPLICANT: Seiichi Araki et al.			
				GROUP ART UNIT: Unknown		EXAMINER: Unknown	
Sheet	2	of	2				

**OTHER ART — NON PATENT LITERATURE DOCUMENTS**

	C7	CHARLES J. FISHER, JR., M.D. et al., "Treatment Of Septic Shock With The Tumor Necrosis Factor Receptor: Fc Fusion Protein," The New England Journal of Medicine, Vol. 334, No. 26, pp. 1697-1702 (June 27, 1996)		
	C8	ROGER C. BONE, M.D., "Sir Isaac Newton, Sepsis, SIRS, and CARS," Crit. Care Med., Vol. 24, No. 7, pp. 1125-1128 (1996)		
	C9	NAVDEEP S. CHANDEL et al., "Role Of Oxidants In NF-κB Activation And TNF-α Gene Transcription Induced By Hypoxia And Endotoxin," The Journal of Immunology, Vol. 165, pp. 1013-1021 (2000)		
	C10	M. SUMIDA et al., "TNF-α And Endotoxin Serum Levels In Cancer Patients Undergoing Intraperitoneal Hyperthermic Perfusion," Int. J. Hyperthermia, Vol. 12, No. 5, pp. 607-615 (1996)		
	C11	MASAHICO HIROTA et al., "Immune Response Induced By Surgical Trauma," Department of Surgery II, Kumamoto University Medical School, Kumamoto, Japan, Vol. 97, No. 9, pp. 721-725 (1996) (English Abstract enclosed)		
	C12	SALGADO, A. et al., "Inflammatory mediators and their influence on haemostasis," <i>Haemostasis</i> , Vol. 24, No. 2, Mar.-Apr. 1994, pp. 132-8.		

EXAMINE R	DATE CONSIDERED
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#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. \_\_, filed \_\_, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

[NOTE - The Office hereby waives the requirement under 37 CFR 1.98 (a)(2)(i) for submitting a copy of each cited U.S. patent and each U.S. patent application publication for all U.S. national patent applications filed after June 30, 2003 and for all international applications that have entered the national stage under 35 USC 371 after June 30, 2003. See 37 CFR 1.491(b). For all patent applications filed on or before June 30, 2003, copies of cited U.S. patents and patent application publications are still required unless an eIDS is filed. Copies of all other patent(s), publication(s), or other information listed must still be provided, even if it was previously submitted to, or cited by, the U.S. Patent Office in an earlier application, unless the earlier application is identified by the IDS and is relied upon for an earlier filing date under 35 U.S.C. §120, and the copy was provided in the earlier application.]